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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/622,272

07/17/2003

Shanta M. Modak

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EXAMINER

ANDERSON, JAMES D

ART UNIT

PAPER NUMBER

1614

NOTIFICATION DATE

DELIVERY MODE

01/22/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DLNYDOCKET@BAKERBOTTS.COM

Office Action Summary	Application No. 10/622,272	Applicant(s) MODAK ET AL.	
	Examiner JAMES D. ANDERSON	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-13, 15, 17, 31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-13, 15, 17, and 31-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Formal Matters

Applicants' response and amendments to the claims, filed 11/21/2008, are acknowledged and entered. Claims 1-9, 11-13, 15, 17, and 31-32 are pending and under examination.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/21/2008 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1-9, 11-13, 15, 17, and 31-32 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103 – New Ground of Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1-4, 6-8, 11-13, 15, 17, and 31-32 as being unpatentable over Modak *et al.* and Dodd *et al.* in view of Luebbe *et al.* is **withdrawn** in light of Applicants' amendment to claim 1, which added the limitation "0.05%-4% (weight/weight) incroquat". The cited references do not teach or suggest the claimed incroquat.

The rejection of claim 5 as being unpatentable over Modak *et al.* and Dodd *et al.* in view of Luebbe *et al.* and further in view of O'Laughlin *et al.* is **withdrawn** in light of Applicants' amendment to claim 1 as discussed *supra*.

The rejection of claim 9 as being unpatentable over Modak *et al.* and Dodd *et al.* in view of Luebbe *et al.* and further in view of Turner *et al.* is **withdrawn** in light of Applicants' amendment to claim 1 as discussed *supra*.

Claims 1-9, 11-13, 15, 17, and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Modak *et al.*** (U.S. Patent No. 5,985,918; Issued Nov. 16, 1999) and **Modak *et al.*** (U.S. Patent No. 5,965,610; Issued Oct. 12, 1999; Filed Jun. 9, 1997) in view of **Wei *et al.*** (U.S. 2002/0098159 A1; Published Jul. 25, 2002; Filed May 18, 2001).

The instant claims recite compositions comprising two or more water-soluble organic salts of zinc, an antimicrobial agent, incroquat, farnesol, and further comprising water, ethanol, and one or more agents selected from the group consisting of a gelling agent, a thickening agent, a hydrophilic or hydrophobic polymer, an emulsifying agent, and an emollient.

Modak *et al.* ('918) teach of the use of organic salts of zinc in anti-irritant topical formulations (Abstract).

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Organic salts of zinc include zinc salicylate, zinc tannate, zinc gluconate, zinc undecylenate, zinc valerate, zinc laurate, zinc stearate, zinc lactate and zinc propionate (col. 1, lines 56-60) as recited in instant claim 2.

The organic salts of zinc may be comprised in a cream base, which may be hydrophilic or hydrophobic (col. 2, lines 8-9). Said cream bases are known to include water, dimethicone, glycerin and other excipients such as vitamin E as recited in claims 5 and 31 (*id.* at lines 10-26).

The concentration of organic salts of zinc may vary from between 1 to 15% and in a particular embodiment, may comprise 0.1 to 1% zinc salicylate (*id.* at lines 27-30 and lines 36-45)). This suggests and motivates the amounts of zinc salts as recited in claim 1.

Further, in addition to zinc salicylate, the compositions may comprise “one or more other organic salts of zinc, thus motivating the inclusion of “two or more” zinc salts as recited in instant claim 1 (*id.* at lines 30-31).

With respect to the amounts of water and emollients recited in the instant claims, if the compositions taught in Modak *et al.* comprise about 1 to 15% organic zinc salt in a cream base, the remaining percentage must be comprised of water and emollients. Modak *et al.* do not teach compositions further comprising incoquat or an antimicrobial compound.

However, Modak *et al.* ('610) teaches zinc gluconate gel-containing topical compositions which have an anti-irritant effect on the skin (Abstract). Said topical compositions further comprise chlorhexidine gluconate (*id.*). Chlorhexidine gluconate is an antimicrobial agent recited in instant claim 11. The compositions of Modak *et al.* can contain anti-microbial agents or combinations of anti-microbial agents (col. 4, lines 57-59) such as benzalkonium chloride and chlorhexidine and salts thereof (col. 5, lines 2-3 and 15-40).

The gels of the topical compositions may be formed from 1-10 percent zinc gluconate, 0.4-4 percent chlorhexidine gluconate and 2 to 20 percent purified water (col. 26, lines 14-18). Such amounts obviate the amounts of zinc salts, antimicrobial agent, and water as recited in claims 1 and 3.

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Creams for use as topical compositions may comprise a water phase comprising 0.05-4 percent Ucare JR-400, which is an emollient as recited in claim 4 and which contains a "polyquaternium compound" as recited in claim 5, 0.5-5 percent crodamol, which is a gelling or thickening agent as recited in claims 6 and 7, and 1-10 percent inicroquat behenyl TMS as recited in claim 1 (col. 26, lines 18-26).

The primary and secondary references thus teach, suggest, and motivate topical compositions comprising two or more zinc salts (*e.g.*, zinc gluconate and zinc salicylate), one or more antimicrobial compounds (*e.g.*, benzalkonium chloride and chlorhexidine gluconate), and further comprising water, ethanol, and one or more agents selected from the group consisting of gelling agents and/or thickening agents (*e.g.*, crodamol), hydrophilic or hydrophobic polymers (*e.g.*, dimethicone), emulsifying agents, and emollients (*e.g.*, UCare JR-400 and/or glycerin). The references do not teach the claimed farnesol claims 1 and 17.

However, Wei *et al.* discloses that benzalkonium chloride is a known non-cationic antimicrobial agent (page 7, [0096-0098]) and that farnesol as recited in claims 1 and 17 and the oils recited in claim 32 and are known naturally occurring antimicrobial agents (pages 9-10, [0256]). Wei *et al.* further teach that the claimed gelling agents, thickening agents, hydrophilic or hydrophobic polymers, emulsifying agents, and emollients are known excipients useful in topical cream compositions. In this regard, Wei *et al.* disclose mildness enhancers including cationic and nonionic polymers, co-surfactants, moisturizers, and mixtures thereof such as polyethylene and polypropylene glycols and silicone polymers in amounts ranging from 0.1 to 1% (page 10, [0260]). Silicone oils such as mixtures of dimethicone and dimethiconol are disclosed at page 10, [0267] and non-volatile silicones ranging from 0.01 to 5% as degreasing agents are disclosed at page 12, [0283]. Stabilizers comprising a polymeric thickener such as hydroxy ethyl cellulose or polyquaternium 10 in amounts ranging from 0.01 to 5% are disclosed at page 13, [0305].

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have formulated a topical composition comprising the claimed excipients. Modak *et al.* ('918) suggest the use of two or more organic zinc salts

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as anti-irritant components of topical compositions. While Modak et al. ('918) do not teach the addition of antimicrobial agents to said topical compositions, Modak et al. ('610) teach topical compositions containing zinc gluconate and one or more antimicrobial agents such as chlorhexidine gluconate also have an anti-irritant effect on the skin. While Modak et al. ('610) suggest that mixtures of antimicrobial agents can be used in the compositions disclosed therein, the inventors do not explicitly recite farnesol. However, they do teach that the term "anti-microbial" agent means any substance which inactivates microbial pathogens. As such, the anti-microbial agents disclosed in Wei et al. are reasonable substitutions and/or additions to the anti-microbial agents explicitly disclosed in Modak et al. ('610).

One of ordinary skill in the art at the time the invention was made would have been imbued with at least a reasonable expectation that addition of one or more anti-microbial agents to the topical compositions disclosed in Modak et al. ('918) would result in a topical composition having anti-microbial activity with minimal irritation based on the combined teachings of the cited references. With respect to the recited gelling agents, thickening agents, hydrophilic or hydrophobic polymers, emulsifying agents, and emollients, such excipients are well established in the art as useful in the formulation of topical compositions as taught by Modak et al. ('918), Modak et al. ('610), and Wei et al. As such, it is well within the purview of the skilled artisan using no more than routine experimentation to combine these agents in suitable amounts in a topical composition.

The implicit motivation to combine to the cited references is based on the fact that Modak et al. and Modak et al. are both drawn to compositions comprising zinc salts for use as anti-irritant topical compositions, optionally containing one or more anti-microbial agents (Modak et al. ('610)). Wei et al. is also drawn to topical compositions containing anti-microbial agents. As such, one skilled in the art could readily envision formulation of a topical composition containing two or more zinc salts as suggested and motivated by Modak et al. ('918) and further containing one or more anti-microbial agents as suggested and motivated by both Modak et al. ('610) and Wei et al. The skilled artisan would expect that two anti-microbial agents would be more effective than only one anti-microbial agent in such compositions.

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Claims 1-9, 11-13, 15, 17, and 31-32 are rejected under 35 U.S.C. 103(a) as being obvious over **Modak et al.** (US 2003/0152644 A1; Published Aug. 14, 2003; Filed Oct. 23, 2001) and **Modak et al.** (U.S. Patent No. 5,985,918; Issued Nov. 16, 1999) in view of **Wei et al.** (U.S. 2002/0098159 A1; Published Jul. 25, 2002; Filed May 18, 2001).

The applied reference (US 2003/0152644 A1) has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Modak et al. ('644) disclose antimicrobial compositions having synergistic combinations of octoxyglycerin and at least one other antimicrobial agent (Abstract). In certain embodiments, skin irritation is minimized by low concentrations of antimicrobials and/or the presence of soothing components such as zinc (id.). Zinc compounds are disclosed to have anti-irritant activity (page 3, [0026]). Preferred zinc compounds are zinc salts such as zinc gluconate, zinc salicylate, zinc acetate, and zinc undecylate as recited in claim 2 (id.). Modak et al. disclose emollients, thickening and/or gelling agents, surfactants, and additional additives such as silicone fluid (e.g., dimethicone), and vitamins (e.g., vitamin E) (page 3, [0027] and [0029]; page 4, [0031] and [0033]). The examples provided in Modak et al. disclose antiseptic gels and aqueous formulations containing, among other ingredients:

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1) 0.8% zinc gluconate, 65% ethanol, 23.13% water, 0.15% Ucare JR 400 (polyquateratum-10), 1.0% incroquat behynyl TMS, 0.5% dimethicone, 1.5% propylene glycol, 1.0% glycerine, 0.05% chlorhexidine digluconate, and 0.12% benzalkonium chloride;

2) 31.32% water, 0.08% UCare, 0.4% incroquat, 63.5% ethanol, 0.4% Glucam E-20, 0.05% chlorhexidine digluconate, and 0.12% benzalkonium chloride; or

3) 30.5% water, 0.4% incroquat, 1.0% propylene glycol, 63.5% ethanol, 0.4% Glucam E-20, 0.05% chlorhexidine digluconate, and 0.12% benzalkonium chloride.

The compositions, which can also contain zinc stearate as recited in claim 7 in an amount of 3.8% (see formulation 3 at page 4), obviate the claimed excipients and amounts of excipients as recited in claims 1-9, 11-13, 15, 17, and 31.

Modak *et al.* ('918) teach of the use of organic salts of zinc in anti-irritant topical formulations (Abstract).

Organic salts of zinc include zinc salicylate, zinc tannate, zinc gluconate, zinc undecylenate, zinc valerate, zinc laurate, zinc stearate, zinc lactate and zinc propionate (col. 1, lines 56-60) as recited in instant claim 2.

The organic salts of zinc may be comprised in a cream base, which may be hydrophilic or hydrophobic (col. 2, lines 8-9). Said cream bases are known to include water, dimethicone, glycerin and other excipients such as vitamin E as recited in claims 5 and 31 (*id.* at lines 10-26).

The concentration of organic salts of zinc may vary from between 1 to 15% and in a particular embodiment, may comprise 0.1 to 1% zinc salicylate (*id.* at lines 27-30 and lines 36-45)). This suggests and motivates the amounts of zinc salts as recited in claim 1.

Further, in addition to zinc salicylate, the compositions may comprise "one or more other organic salts of zinc, thus motivating the inclusion of "two or more" zinc salts as recited in instant claim 1 (*id.* at lines 30-31).

Neither the primary or secondary reference teaches adding farnesol to the compositions disclosed therein.

However, Wei *et al.* discloses that farnesol as recited in claims 1 and 17 and the oils recited in claim 32 and are known naturally occurring antimicrobial agents (pages 9-

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10, [0256]). Wei *et al.* further teach that the claimed gelling agents, thickening agents, hydrophilic or hydrophobic polymers, emulsifying agents, and emollients are known excipients useful in topical cream compositions. In this regard, Wei *et al.* disclose mildness enhancers including cationic and nonionic polymers, co-surfactants, moisturizers, and mixtures thereof such as polyethylene and polypropylene glycols and silicone polymers in amounts ranging from 0.1 to 1% (page 10, [0260]). Silicone oils such as mixtures of dimethicone and dimethiconol are disclosed at page 10, [0267] and non-volatile silicones ranging from 0.01 to 5% as degreasing agents are disclosed at page 12, [0283]. Stabilizers comprising a polymeric thickener such as hydroxy ethyl cellulose or polyquaternium 10 in amounts ranging from 0.01 to 5% are disclosed at page 13, [0305].

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have formulated a topical composition comprising the claimed excipients. Modak et al. ('644) disclose antimicrobial compositions having synergistic combinations of octoxyglycerin and at least one other antimicrobial agent wherein skin irritation is minimized by low concentrations of antimicrobials and/or the presence of soothing components such as zinc. Modak et al. ('918) suggest the use of two or more organic zinc salts as anti-irritant components of topical compositions. While Modak et al. ('644) suggest that mixtures of preferably at two antimicrobial agents can be used in the compositions disclosed therein, the inventors do not explicitly recite farnesol. However, the anti-microbial agents disclosed in Wei et al. are reasonable substitutions and/or additions to the anti-microbial agents explicitly disclosed in Modak et al. ('644).

One of ordinary skill in the art at the time the invention was made would have been imbued with at least a reasonable expectation that addition of two or more zinc salts to the antimicrobial topical compositions disclosed in Modak et al. ('644) would result in a topical composition having anti-microbial activity with minimal irritation based on the combined teachings of the cited references. With respect to the recited gelling agents, thickening agents, hydrophilic or hydrophobic polymers, emulsifying agents, and emollients, such excipients are well established in the art as useful in the formulation of topical compositions as taught by Modak et al. ('644), Modak et al. ('918), and Wei et al.

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As such, it is well within the purview of the skilled artisan using no more than routine experimentation to combine these agents in suitable amounts in a topical composition.

The implicit motivation to combine to the cited references is based on the fact that Modak et al. and Modak et al. are both drawn to compositions comprising zinc salts for use as anti-irritant topical compositions, optionally containing one or more anti-microbial agents (Modak et al. ('644)). Wei et al. is also drawn to topical compositions containing anti-microbial agents. As such, one skilled in the art could readily envision formulation of a topical composition containing two or more zinc salts as suggested and motivated by Modak et al. ('918) and further containing one or more anti-microbial agents as suggested and motivated by both Modak et al. ('644) and Wei et al. The skilled artisan would expect that two anti-microbial agents would be more effective than only one anti-microbial agent in such compositions.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES D. ANDERSON whose telephone number is (571)272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/James D Anderson/

Examiner, Art Unit 1614